IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN N-NITROSODIMETHYLAMINE (NDMA) CONTAMINATION PRODUCTS LIABILITY LITIGATION	Civil No. 19-2875 (RBK/JS)

CORE DISCOVERY ORDER FOR LOSARTAN AND IRBESARTAN

The Court having conducted a conference with the parties on July 13, 2022; and this Order intending to confirm the Court's rulings regarding the production of "core discovery"[1] and other issues; and good cause existing for the entry of this Order; and accordingly,

IT IS HEREBY ORDERED this 18th day of July, 2022, as follows:

1. This Order regarding the production of "core" discovery shall only apply to API manufacturer and supplier defendants. This Order shall also apply to finished product/dose manufacturer defendants. Hereinafter, these defendants shall be collectively referred to as the "responding defendants." To the extent core discovery is not produced by the responding defendants, defendants who are U.S. agents for the purpose of FDA communications shall produce the discovery.

2. The responding defendants shall only produce core discovery concerning the facilities that manufactured the API used in losartan and irbesartan or the finished products at issue in the litigation. The responding defendants shall also produce a list of the responsive facilities.

3. This Order pertains to the core discovery for losartan and irbesartan.

4. The scope of responsive material for purposes of the losartan and irbesartan products at issue in this Order shall be limited in accordance with the Court's rulings on "macro" discovery issues for valsartan products memorialized in the Court's November 25, 2019 Order (ECF No. 303).

5. The responding defendants shall organize the documents in a manner that facilitates their identification in accordance with the categories set forth below.

6. The following are the categories of core discovery for purposes of losartan and irbesartan:

[1] The Court defines "core discovery" as discovery that is (1) easily identifiable, (2) unquestionably relevant and not privileged, (3) relatively simple to retrieve, and (4) discrete. Even if a subject area does not meet the criteria of core discovery, it does not necessarily mean the area is off-limits to Fed. R. Civ. P. 26(b)(1) discovery.

a. For API Manufacturer and Supplier Defendants[2]

i. Approved losartan and irbesartan ANDA file(s) for products intended to be marketed and/or sold in the United States at any time prior to the losartan and irbesartan product recalls at issue.
ii. Approved losartan and irbesartan Drug Master File(s) for products intended to be marketed and/or sold in the United States at any time prior to the losartan and irbesartan product recalls at issue.
iii. Communications with the FDA relating to or concerning: (A) the ARB recalls, (B) the investigation into the cause of the alleged contamination, (C) efforts to contain, remove or detect the contamination, (D) supplements to the losartan and irbesartan Drug Master File re: manufacturing process changes for the time period agreed to for each responding defendant by the plaintiffs and such defendant, (E) all FDA Form 483's,[3] Establishment Inspection Reports, CGMP inspection reports, and warning letters, as well as the responding defendants' responses to same, regarding any facility that manufactured or supplied the API at issue, and (F) a list of all United States customers for the time period agreed to for each responding defendant by the plaintiffs and such defendant.
iv. To the extent a responding defendant contends it does not have possession, custody or control of any of the listed documents, it shall identify where the documents are located.
v. All nitrosamine test results.

b. For Finished Product/Dose Manufacturer Defendants[4]

i. Approved ANDA file for each involved finished dosage formulation product intended to be marketed and/or sold in the United States at any time prior to the losartan and irbesartan product recalls at issue.
ii. Communications with the FDA described in subparagraph a.iii. to the extent not produced by another responding defendant.
iii. To the extent a responding defendant contends it does not have possession, custody or control of any of the listed documents, it shall identify where the documents are located.

[2] Pursuant to the approved Short Form Complaint memorialized in Case Management Order No. 24 (ECF No. 914), the identified defendants that are API Manufacturer and Supplier Defendants with respect to losartan products are: Hetero Drugs, Ltd., Hetero Labs, Ltd., and Zhejiang Huahai Pharmaceutical Co., Ltd. The identified API Manufacturers and Suppliers with respect to irbesartan products are: Aurobindo Pharma, Ltd. and Zhejiang Huahai Pharmaceutical Co. Ltd.
[3] Including any reply to FDA Form 483, related subsequent correspondence; the FDA inspection reports and exhibits; responses to that report and exhibits; and any related FDA correspondence and meeting minutes.
[4] Pursuant to the approved Short Form Complaint memorialized in Case Management Order No. 24 (ECF No. 914), the identified defendants that are Finished Product/Dose Manufacturer Defendants with respect to losartan products are: Hetero Labs, Ltd., Macleods Pharmaceuticals, Ltd., Macleods Pharma USA, Inc., Sandoz Inc., Teva Pharmaceutical Industries Ltd., Torrent Pharmaceuticals, Ltd., Vivimed Life Sciences Pvt. Ltd., and Zhejiang Huahai Pharmaceutical Co., Ltd. The identified Finished Product/Dose Manufacturer Defendants with respect to irbesartan products are: Aurolife Pharma, LLC, ScieGen Pharmaceuticals, Inc., U.S., and Zhejiang Huahai Pharmaceutical Co. Ltd.

iv. All nitrosamine test results.

c. For U.S. Agents for FDA Communications Defendants

i. To the extent not produced by another responding defendant, the discovery listed in subparagraphs a. and b. above.
ii. To the extent a responding defendant contends it does not have possession, custody or control of any of the listed documents, it shall identify where the documents are located.

7. Responding defendants will produce the foregoing on a rolling basis to be completed within 90 days of the entry of this order. To the extent that a responding defendant(s) encounters unforeseen burdens in connection with producing documents within this time frame, such defendant(s) shall meet and confer with plaintiffs and raise any issues that cannot be resolved with the Court.

8. In addition to the core discovery, plaintiffs have requested sales and pricing data for losartan and/or irbesartan products, and responding defendants have agreed to produce such data consistent with the information requested with respect to valsartan products in Court-approved RFP 107 (ECF. No. 328 at Exh. A, p. 12). At plaintiffs' request, responding defendants will prioritize collection and production of this information.

9. The parties shall meet and confer to identify an agreed-upon relevant time period for each responding defendant in accordance with the approach set forth in the Court's oral opinion as reflected on the transcript of the November 20, 2019 Case Management Conference (*see id.* at 4).

10. Without the need for a separate discovery request, and no later than fourteen (14) days after the date it sends to the FDA or receives from the FDA a communication regarding the (1) ARB recall, (2) the investigation into the cause of the alleged contamination, and (3) efforts to contain, remove or detect the contamination, the responding defendants shall serve plaintiffs with a copy of the responsive communication.[5]

s/ Thomas I. Vanaskie
Hon. Thomas I. Vanaskie (Ret.)
Special Master

Dated: July 18, 2022

[5] This provision is modeled after Local Patent Rule 3.6(j).